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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/003,136

Applicant(s)

WONG-MADDEN ET AL.

Examiner

Christian L. Fronda

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7,10,11 and 14-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7,10,11 and 14-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Claims 7, 10, 11, 14-18 are pending and under consideration in this Office Action.

The amendment filed 05/09/2005 is an informal amendment since all the claims have not been listed, specifically claims 1-6. Applicant is required to list all of the claims and indicate the status of each claim (e.g., cancelled, amended, etc).

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 16, 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 recites the phrase "determining the defined substrate specificity using a fluorescent chromophore" which is vague and indefinite. The metes and bounds of the phrase are not clear since it is not certain how a fluorescent chromophore can be used to determine substrate specificity as recited in the claim.

Furthermore, there is insufficient antecedent basis for this limitation in the claim. Claim 17 is also rejected because it does not correct the defect of claim 16.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 7, 10, 11, 14-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Applicants' arguments filed 05/09/2005 have been fully considered but are not persuasive. Applicants' position is that characteristics of exoglycosidases from *Xanthomonas* species including their source and substrate specificity have been described in the application and that structural differences between exoglycosidases are not relevant to the claimed method. The examiner respectfully disagrees for reasons of record as supplemented below.

In the evaluation of the claims for compliance with the written description requirement of 35 U.S.C. 112, of particular relevance is 66 FR 1099, Friday, January 5, 2001, which states: "*Eli Lilly* explains that a chemical compound's name does not necessarily convey a written description of the named chemical compound, particularly when a genus of compounds is claimed. *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1405. The name, if it does no more than distinguish the claimed genus from all others by function, does not satisfy the written description requirement because "it does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. Thus *Eli Lilly* identified a set of circumstances in which the words of the claim did not, without more, adequately convey to others that applicants had possession of what they claimed." (see p. 1100, 1st column, line 47 to 2nd column, line 2).

The claims are directed toward a method using several genera: a genus of fucosidases, a genus of mannosidases, a genus of xylosidase, a genus of glucosidase, a genus of galactosidases, a genus of N-acetylglucosaminidases, and a genus of hexosaminidases.

The recitation of the names such as "fucosidase", "mannosidase", and "xylosidase" and that they are obtainable from the recited *Xanthomonas* species does not define any structural features commonly possessed by each claimed genus that distinguish them from others. Furthermore, the specification does not describe and define any structural features commonly possessed by each genus. Thus, one skilled in the art cannot visualize or recognize the identity of the members of each genus.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definitions, such as the structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997), quoting *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe the genus of

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genetic materials, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g. structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these. Therefore, the instant claims are not adequately described.

In view of the above considerations, one of skill in the art would not recognize that applicants were in possession of each genus used in the claimed method.

Claim Rejections - 35 U.S.C. § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 7, 10, 14, 15, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ichikawa et al. (Anal Biochem. 1992 May 1;202(2):215-38) in view Frank et al. (Applied and Environmental Microbiology (1979), 38(3), 554-6) and Su et al. (Journal of Biotechnology (1989), 9(2), 139-52).

Applicants' arguments filed 05/09/2005 have been fully considered but are not persuasive. Applicants' position is that there is no teachings from any of the references to suggest combining the references, there is no motivation to combine the references, that if the references were combined they would not teach the claimed invention, and there is no teaching from the references to use an exoglycosidase from *Xanthomonas* to alter immunogenic properties of carbohydrates by cleavage. The examiner respectfully disagrees for reasons of record as supplemented below.

As stated in the previous Office Action, Ichikawa et al. teach methods for enzyme-catalyzed oligosaccharide and carbohydrate synthesis using a fucosidase, mannosidase, xylosidase, glucosidase, galactosidase, N-acetylglucosaminidase, or hexosaminidase which cleaves at a selected glycosidic bond between constituent monosaccharides of the carbohydrate thereby producing a modified carbohydrate which may then be subjected to other enzymes for the

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purposes of making other carbohydrates (see entire publication, especially pp. 228-235).

Ichikawa et al. provide motivation for using glycosidases instead of glycosyltransferases in that that expensive sugar donors are not required to achieve reaction and that glycosidases are generally more available and less expensive than glycosyltransferases.

Regarding the teachings of Frank et al. and Su et al., it is within the purview of one of ordinary skill in the art to use well established chromatography methods to isolate and purify the beta-galactosidase from *Xanthomonas campestris* as taught by Frank et al. and the beta-glucosidase from *Xanthomonas albilineans* as taught by Su et al.

Thus, one of ordinary skill in the art at the time the invention was made would have been motivated to modify the method of Ichikawa et al. such that the that a purified beta-galactosidase from *Xanthomonas campestris* as taught by Frank et al. or purified the beta-glucosidase from *Xanthomonas albilineans* as taught by Su et al. is contacted with a suitable carbohydrate substrate in order to produce a modified carbohydrate product which inherently would have immunogenic properties that are different or altered compared to the original carbohydrate substrate. This modified method of Ichikawa et al. has all the limitations of the claims.

The Examiner has determined the scope and contents of the prior art, ascertained the differences between the prior art and the claims at issue, and found the claimed invention to have been obvious in light of the combined teachings of the references.

In regard to claim 18, it is within the purview of one of ordinary skill in the art to use thin layer silica gel chromatography for the purpose of identifying and measuring the reaction products during the glycosidase reaction.

Conclusion

8. No claim is allowed.

9. Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37


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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF


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